FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC)

AGENDA

September 16, 2009

8:30 a.m.	Call to Order Introduction of Committee	**Kathleen O'Neil, M.D.** Chair, AAC
	Conflict of Interest Statement	**Nicole Vesely, Pharm.D.** Designated Federal Official, AAC
8:40 a.m.	AAC Member Appreciation	**Bob Rappaport, M.D.** Director, Division of Anesthesia, Analgesia and Rheumatology Products, CDER/FDA
8:45 a.m.	Opening Remarks	**Sarah Okada, M.D.** Clinical Team Leader, Division of Anesthesia, Analgesia and Rheumatology Products (DAARP), CDER/FDA

On September 16, 2009, the committee will discuss biologics license application (BLA) 125338, clostridial collagenase, Auxilium Pharmaceuticals, Inc., for the proposed treatment of advanced Dupuytren's disease.

8:50 a.m.	**Sponsor Presentation** Introduction	**Auxilium Pharmaceuticals, Inc.** **Benjamin Del Tito, Ph.D.** Senior Vice President, Quality and Regulatory Affairs Auxilium Pharmaceuticals, Inc.
	Dupuytren's Disease and Current Management	**F. Thomas D. Kaplan, M.D.** Indiana Hand Center Clinical Associate Professor of Orthopedic Surgery Indiana University School of Medicine
	AA4500 Clinical Efficacy	**Anthony DelConte, M.D.** Chief Medical Officer Auxilium Pharmaceuticals, Inc.
	AA4500 Clinical Safety Risk Mgmt Activities	**James Tursi, M.D.** Vice President, Clinical Affairs Auxilium Pharmaceuticals, Inc.
	Benefit/Risk Profile	**Anthony DelConte, M.D.**
10:20 a.m.	*Questions from the Committee to the Sponsor*	
10:35 a.m.	Break	

Arthritis Advisory Committee (AAC)

AGENDA (continued)

September 16, 2009

10:50 a.m.	**FDA Presentation** Collagenase clostridium histolyticum for the proposed treatment of advanced Dupuytren's disease	**BLA 125338** **Eric Brodsky, M.D.** Clinical Reviewer, DAARP, CDER/FDA
	Risk Management Considerations in the FDA Approval Process	**Kathryn O'Connell, M.D., Ph.D.** Drug Risk Management Analyst, OSE/CDER/FDA
11:30 a.m.	*Questions from the Committee to the FDA*	
11:45 a.m.	Lunch	
12:45 p.m.	Open Public Hearing	
1:45 p.m.	*Questions to the AAC and AAC Discussion*	
3:15 p.m.	Adjourn	